amount as previously discussed. Indeed, the specification discloses specific examples of dietary proteins and amounts thereof illustrative of the claimed invention. For example, Example 1 details how three types of protein hydrolysates can be made according to an embodiment of the present invention. Further, the specification discloses on page 6 at lines 10-14 that the source of dietary protein preferably provides about 5% to about 30% of the energy of the nutritional formula where the remaining energy may be provided in the form of carbohydrates and fats. In view of same, the present invention as claimed and as supported in the specification clearly would provide one skilled in the art with a sufficient amount of guidance to make a nutritional composition with a specific amount and type of dietary protein and administer same to a mammal as required by the claimed invention. Contrary to the Patent Office's apparent position, this is all that is required to promote recovery of an organ including a small intestine as required by the claimed invention. In view of same, one skilled in the art clearly would be able to practice the claimed invention without undue experimentation. Therefore, Applicants believe that the enablement requirement has been satisfied based on these reasons alone.

Even assuming that further instruction and guidance than discussed above is necessary to establish enablement, Applicants have conducted a number of experiments detailed in the present application that clearly demonstrate the selective and beneficial effect of a dietary protein on the growth or recovery of an organ including the small intestine. For example, Example 2 details a number of experiments that demonstrate the desirable effect of a dietary protein administered to a mammal on, for example, weight (See, specification, page 17) and protein synthesis rate (See, specification, pages 22 and 23) associated with an organ, such as the small intestine.

In particular, the experiments were conducted with five different feed compositions, namely Feed 1-Feed 5. Each of the feed compositions include substantially the same ingredients except for the protein source. The Feed 1 protein source included a whole protein derived from whey protein; the Feed 2 protein source included a protein hydrolysate (Hydrolysate 1) derived from whey protein that had a degree of hydrolysis of about 14%; the Feed 3 protein source included a protein hydrolysate (Hydrolysate 2) derived from whey protein with a degree of hydrolysis of about 17.3%; the Feed 4 protein source included a protein hydrolysate (Hydrolysate 3) with a degree of hydrolysis of about 35%; and the Feed 5 protein source included free amino acids. See, specification, pages 9-15. The test feed compositions were fed to a group of 40 male, Sprague Dawley rats pursuant to the experimental protocol as detailed on pages 15 and 16 of the specification.

After the feed test period, a number of different experimental parameters, such as weight and protein synthesis rate, were evaluated. As shown in the table on page 17 of the specification, the relative weight of the whole intestine of the rats is significantly ($P<0.05$) higher with Feed 4 as compared to the other feed compositions. Further, the relative weight of the jejunum of the rats is significantly ($P<0.05$) higher with Feed 3, Feed 4, and Feed 5 as compared to the other feed compositions. As shown in the table on page 22 of the specification, Feed 4 had a significant effect ($P<0.05$) on the protein synthesis rate in the duodenum as compared to the other feed compositions. As shown in the table on page 23 of the specification, the rate of protein synthesis, the daily protein synthesis, and the ribosomal efficacy were significantly ($P<0.05$) higher with Feed 3, Feed 4 and Feed 5 as compared to Feed 1 and Feed 2.

Applicants believe the above-described tests clearly suggest that the administration of a dietary protein in an effective amount to a mammal can promote growth or recovery of an organ, such as the small intestine, as required by the claimed invention. At the outset, Applicants' tests clearly demonstrate that an increase in, for example, the weight and protein synthesis rate associated with an organ, such as the small intestine, can be attributed to the administration of a dietary protein as required by the claimed invention. As previously discussed, the test feed compositions were essentially the same except for the protein source. While ingredients of the test feed compositions, such as lipids, may slightly vary between the test feed compositions, clearly one skilled in the art would recognize that the protein source was the only ingredient that was varied in a statistically relevant way contrary to the Patent Office's position. Therefore, Applicants believe that the test results described in the present application are based on correct statistics, and significant effects, when reported, can be ascribed to the respective variable factor mentioned in this context, that is, the protein source.

As previously discussed, the test feed compositions with a protein source that included a protein hydrolysate with a degree of hydrolysis of about 17.3% or greater or that included free amino acids had an increased effect on weight of the intestine, such as the jejunum, as compared to the other test feed compositions. With respect to the duodenum, the test feed composition with a protein source that included a protein hydrolysate with the highest degree of hydrolysis as compared to the other test feed compositions had an increased effect on the protein synthesis rate. Further, the test feed compositions with a protein source that included a protein hydrolysate with a degree of hydrolysis of about 17.3% or greater or that included free amino acids had an increased effect on the protein synthesis rate, the daily protein synthesis, and the ribosomal

efficacy. Therefore, one skilled in the art viewing same would clearly recognize that the increase in, for example, weight and protein synthesis rate of the small intestine as discussed above can be attributed to the administration of a dietary protein as required by the claimed invention.

Contrary to the Patent Office's position, an increase in, for example, the weight and protein synthesis rate due to the administration of the dietary protein is predictive of the recovery or growth of an organ including the small intestine. Indeed, one skilled in the art would readily recognize that growth or the recovery of an organ can be assessed by evaluating, for example, the weight and the protein synthesis rate associated with the organ. As previously discussed, Applicants' experiments clearly demonstrate that the administration of a dietary protein can have an enhanced effect on, for example, the weight and the protein synthesis rate. Therefore, Applicants believe that the claimed invention is enabled and thus satisfies the requirements of 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, second paragraph. The Patent Office alleges that some of the claim terms are unclear in meaning.

Applicants believe that this rejection is improper. Of course, "[p]atent law allows the inventor to be his own lexicographer...[T]he specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification." *United States v. Telectronics, Inc.*, 8 USPQ2d 1217,1220 (Fed.Cir. 1988). In this regard, Applicants believe that the claim terms at issue are clear in meaning as fully supported by the specification.

With respect to the term "recovery", the specification discloses, for example, on page 3 at lines 25-27 that the present invention can be used to treat patients suffering from illnesses or damage to an organ, such as the duodenum and jejunum, and to promote recovery of same due to such illnesses or damage. With respect to the term "selecting a dietary protein selected from...a protein hydrolysate...,one or more free amino acids and mixtures thereof", the specification discloses, for example, on page 6 at lines 1-2 that the dietary protein may also be in the form of a mix of free amino acids, preferably such that the mix provides a balanced amino acid profile. With respect to the term "degree of hydrolysis", the specification discloses, for example, on page 5 at lines 3-5 that "degree of hydrolysis" means the percentage of nitrogen in the form of amino-nitrogen as compared to total nitrogen.

Based on at least these noted reasons, Applicants believe that the claims, as presently pending, satisfy the requirements pursuant to 35 U.S.C. §112, second paragraph. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103. More specifically, claims 30, 32, 35 and 37-41 are rejected in view of U.S. Patent No. 5,679,771 (*Ballard*) and *Duguay* (Journal of Biological Chemistry 270 (29) 17566-74 (1995)); claims 30, 32, 35, 37, 38, 40 and 41 are rejected in view *Ballard* and U.S. Patent No. 5,614,219 (*Wunderlich*); claims 30, 32, 35 and 37-41 are rejected in view of *Mukai Abstract* (English Abstract of JP-3264525); claims 30, 32, 35 and 37-41 are rejected in view of *Mukai* (JP-3264525); claim 30 is rejected in view of *Goldberg* (Horm Metab Res 12 (3), 94-96 (1980)); claim 30 is rejected in view of U.S. Patent No. 5,580,903 (*Mawatari*); and claim 30 is rejected in view of U.S. Patent No. 5,221,668 (*Henningfield*).

Of the pending claims at issue, claim 30 is the sole independent claim as previously discussed. Claim 30 recites a method for promoting recovery of an organ or a mammal. The method includes the steps of selecting a dietary protein that is selected from the group consisting of a protein hydrolysate that has a specific degree of hydrolysis, one or more free amino acids and mixtures thereof; and administering a therapeutically effective amount of the dietary protein to the mammal. All of the remaining claims at issue depend from claim 30 either directly or indirectly and thus as a matter of law incorporate each of the features as required by claim 30.

Applicants have discovered that the form in which dietary protein is provided can have a selective and beneficial effect on the protein concentration, RNA concentration, ribosomal efficacy, rate of protein synthesis, weight, and/or other suitable factors associated with a variety of different organs including the small intestine. This offers the advantage of being able to promote the growth or recovery of a particular organ by providing the dietary protein in a form which can increase the protein concentration, the rate of protein synthesis, and/or other factors in that organ. See, specification pg. 2, at lines 24-29.

Without being bound to any specific theory, it is believed that protein hydrolysates that have a higher degree of hydrolysis can rapidly digest and thus be absorbed in the upper small intestine. In this regard, the protein substrate thus administered is available for protein synthesis in the upper small intestine and thus the upper small intestine may be targeted.

Further, intact protein and protein hydrolysates that have a lower degree of hydrolysis can take longer to digest and thus are more slowly absorbed in the lower small intestine. Therefore,

the protein substrate thus administered is effectively available for protein synthesis in the lower small intestine. Moreover, the lower rate of absorption may result in an enhanced availability of the protein substrate for protein synthesis in the muscles due to the decrease in liver oxidation. In this way, the lower small intestine and muscles may be targeted. Thus, the present invention provided improved methods for promoting the recovery or growth of a targeted organ, such as the small intestine.

Applicants believe that the cited art, even if combinable in any hypothetical combination, fails to disclose or suggest at least the number of features of the claimed invention. With respect to the rejection, in view of *Ballard* and *Duguay*, both references merely relate to the use of IGF-1 as even admitted by the Patent Office. In general, IGF-1 is a hormone, that is, a substance that occurs in the human or animal body in miniscule quantities, thus having an effect at a specific target position, such as a cell, organ or the like. Indeed, a dietary protein, let alone a dietary protein composed of a protein hydrolysate, free amino acids or mixtures thereof that can be administered to a mammal to promote growth or recovery in a target organ, as required by the claimed invention is clearly distinguishable from other proteins, such as the peptide-hormone disclosed in *Ballard* and *Duguay*, that are typically not intended for diet as a dietary application of such other proteins may be nonsensical and/or even dangerous to do so.

In contrast, the claimed dietary protein includes proteins that have a nutritive purpose, that is, proteins that are known and generally accepted to be used as macro-nutrients and proteinogenic matter in nutrition as one skilled in the art would understand. For example, Applicants' specification on page 5 at lines 12 – 16 discloses that the claimed dietary protein can include animal proteins, such as milk proteins, meat proteins and egg proteins; vegetable proteins, such as soy protein, wheat protein, rice protein and pea protein; mixtures of free amino acids (or combinations thereof); and milk proteins, such as casein and whey proteins. In view of same, clearly one skilled in the art would consider the dietary protein as claimed to be distinguishable from the IGF-1 hormones as disclosed in *Ballard* and *Duguay*. Thus, for at least these reasons, Applicants believe that *Ballard* and *Duguay*, even if combinable, are deficient with respect to the claimed invention.

With respect to the rejection in view of *Ballard* and *Wunderlich*, again, *Ballard* is clearly deficient whether with respect to the claimed invention as previously discussed. Further, the Patent Office merely relies on *Wunderlich* for its purported teachings regarding pharmaceutical formulations that contain peptides or proteins in combination with gelatin. Therefore, even if

combinable, Applicants believe that *Ballard* and *Wunderlich* are deficient with respect to the claimed invention.

With respect to *Mukai* including the English Abstract thereof, the primary focus of this reference relates to di-peptides that allegedly prevent catabolism of muscular proteins. For this purpose, the peptides of *Mukai* have to be synthetically synthesized. This adds costs and complexity to the process.

Indeed, the claimed invention provides that a dietary protein, thus administered, can effectively promote the growth or recovery of a targeted or specific organ including the small intestine. The dietary protein as claimed is composed of a protein hydrolysate, free amino acids or combinations thereof. Clearly, nowhere does *Mukai* disclose or suggest at least such features as required by the claimed invention. Therefore, Applicants believe that the *Mukai* reference including the English Language Abstract thereof is clearly deficient with respect to the claimed invention.

With respect to the *Goldberg* reference, its primary focus relates to processed blood plasma extracts that purportedly can be attributed to an increase in DNA synthesis in liver cells. See, *Goldberg*, summary. Clearly, one skilled in the art would regard processed blood plasma extracts as disclosed in *Goldberg* to be distinguishable from the dietary protein as required by the claimed invention. Based on at least this reason, the *Goldberg* reference is deficient with respect to the claimed invention.

With respect to both the *Mawatari* and *Henningfield* reference, the Patent Office asserts that the disclosures relating to specific amino acids would necessarily render obvious the dietary protein features as required by the claimed invention. The purported teachings of *Mawatari* and *Heningfield* clearly contrast the dietary protein as claimed that it is composed of protein hydrolysate, free amino acids that can provide a balance amino acid profile and mixtures thereof wherein thus administered can promote the growth or recovery of a targeted or specific organ as clearly demonstrated by the Applicants as discussed above. Therefore, these references are deficient with respect to the claimed invention.

Based on at least these noted reasons, Applicants believe that the cited art, even if combinable in any hypothetical combination, fail to disclose or suggest a number of features of the claimed invention. Therefore, Applicants respectfully submit that the cited art fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

Applicants note for the record that the Examiner did not initial two foreign patent documents listed on Applicants' IDS, namely, EP017867 and EP0322589A1. In response, Applicants are submitting herewith a Supplemental IDS that identifies two U.S. patents which are equivalent to the European patents discussed above. In particular, U.S. Patent No. 4,330,528 is equivalent to EP 017867, and U.S. Patent No. 5,039,532 is equivalent to EP0322589. Therefore, Applicants respectfully request that these references be considered during examination of the above-referenced application.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit consideration of same.

Respectfully submitted,

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